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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



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Applicant's or agent's file reference E03-004	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. <b>PCT/KR2003/002163</b>	International filing date (day/month/year) <b>17 OCTOBER 2003 (17.10.2003)</b>	Priority date (day/month/year) <b>17 OCTOBER 2002 (17.10.2002)</b>
International Patent Classification (IPC) or national classification and IPC  <b>IPC7 C12N 15/63, A61K 39/12, A61K 31/00</b>		
Applicant  <b>BIOLEADERS CORPORATION et al</b>		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.  <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  These annexes consist of a total of _____ sheets.
3. This report contains indications relating to the following items:  I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand  <b>14 MAY 2004 (14.05.2004)</b>	Date of completion of this report  <b>17 DECEMBER 2004 (17.12.2004)</b>
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer  HAN, Hyung Mee Telephone No. 82-42-481-5601 

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/KR2003/002163

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☐ the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement) under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language English which is

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☒ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets \_\_\_\_\_

## 5.

- ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed," and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION

International application No.

PCT/KR2003/002163

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	<u>1-23</u>	<u>YES</u>
	Claims	<u>None</u>	<u>NO</u>
Inventive step (IS)	Claims	<u>1-23</u>	<u>YES</u>
	Claims	<u>None</u>	<u>NO</u>
Industrial applicability (IA)	Claims	<u>1-23</u>	<u>YES</u>
	Claims	<u>None</u>	<u>NO</u>

**2. Citations and explanations (Rule 70.7)**

The present invention relates to surface display vectors containing one or more genes selected among pgs B, pgs C and pgs A, encoding a poly-gamma-glutamic acid synthetase complex (pgs BCA) of a Bacillus sp. strain and genes encoding viron capsid proteins, tumor-associated proteins of human papillomavirus, and a method for preparing the same. The present invention also relates to the microbe transformed with the said vector and a vaccine containing crude antigen protein extracts or antigen proteins purified from the said microbes.

The following documents have been considered for the purpose of this report:

D1: WO 99/01557 (14 Jan. 1999)

D2: WO 00/75336 (14 Dec. 2000)

D3: Neoplasma 49(5): 285-289 (2002)

D4: Biochem. Biophys. Res. Commun. 263(1): 6-12 (1999)

**1. Novelty and Inventive Step**

D1 describes human papilloma virus (HPV) capsomeres which express at least one virus-neutralizing conformational epitope of a native HPV L1 protein. D2 discloses polypeptidic protein fragments of E6 and E7 HPV proteins, a method for the production and the use thereof in the field of vaccination. D3 relates to therapeutic vaccines against HPV 16-associated tumors. D4 describes a gene encoding poly-gamma-glutamate synthetase. D1-D4 describe the general state of the art. None of the prior art documents teach or suggest vectors containing genes encoding a poly-gamma-glutamic acid synthetase complex (pgs BCA) and genes encoding human papillomavirus, the microbe transformed with the said vector and a vaccine containing antigen proteins purified from the said microbes. Therefore, the subject-matter of claims 1-23 is considered to be novel and to involve an inventive step under PCT Article 33(2) and 33(3).

**2. Industrial Applicability**

The subject-matter of claims 1-23 is considered to be industrially applicable under PCT Article 33(4).